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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,347	03/25/2004	David A. Krantz	51637-75	5440

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KENYON & KENYON LLP  
1500 K STREET N.W.  
SUITE 700  
WASHINGTON, DC 20005

EXAMINER
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JAWORSKI, FRANCIS J

ART UNIT	PAPER NUMBER
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3768

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/808,347

Applicant(s)

KRANTZ ET AL.

Examiner

Jaworski Francis J.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2006.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-26 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

Parenthesized claim numbers following argument portions pertain to the specific claim or claims to which the arguments are directed.

[ *Italicized portions highlight wording additions referenced to the Office action mailed on December 20, 2005.*]

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 5, 7, 11 – 17, 25-26 are *again* rejected under 35 U.S.C. 102(b) as being anticipated by Weiss et al (US5740266).

Weiss et al is directed to a method and system apparatus for analyzing a fetal skull image to assess spina bifida risk, comprising

receiving all coordinates of the image via a frame grabber or skull mark points via imaging system 10 or a graphic input device,

determining mathematical curvature coefficients for a cropped image outline of the skull, and

using the curvature values to provide a 'figure of merit' or single-valued measurement marker for indication of spina bifida, see col. 9 lines 23-38.

*Note that in Figure 27, Weiss et al effect an inverse mathematical function to emphasize the skull shape depression abnormality with more predictability. Hence at each point around the fetal circumference, Fig. 27 represents a normalized function such that the plotted representative value times the measured curvature by definition would result in "1", and these curvature coefficients of the individual's skull (although not explicitly called such) compositely serve as a marker for the risk of spina bifida when they factor in to the composite percentage below threshold time versus the norm in Fig. 28. (claims 1, 4, 7).*

An analogous mask measurement may be practiced to detect Down's syndrome chromosomal abnormality disorder, see col. 9 lines 55-60. (claims 2-3).

The video display 17 (misnumbered as '15' in the specification) is a computer monitor, see col. 7 lines 1-7. (claim 5).

The determined coefficient parameterizations are compared to statistical population norms serving as index values, see 81, 82 of Fig. 28. (Claims 11 – 14, 17).

Risk is calculated from these statistical distributions, see col. 9 lines 45 – 48. This is effectively a likelihood ratio as X chances per hundred (Claim 15 -16).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6, 21 – 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al as applied to claim 1 above, and further in view of Jeffery et al (Amer. Jrnl Phys. Anthr.123:78-90, of record with the IDS filed May 5, 2005), or Tamez-Pena et al (US6836557). Whereas the former is silent as to three-dimensional image origins for a biomarker measurement, it would have been obvious in view of Jeffery page 81 Fig. 1 to use three-dimensional e.g. MRI imaging in order to in general characterize a fetal skull. Alternatively, Tamez-Pina et al evidence col. 1 lines 26-28 and col. 2 lines 11-56 that 3D e.g. MRI imaging for purposes of automated biomarker identification would have been well-known as a basis for providing accurate anatomic skull measurements. (claim 6).

Since Weiss et al suggests aligning the skull as an object and determining its major and minor axes, it would have been obvious to organize the image along coordinate axes in 3D to effect these object transforms. Population-based statistical analysis is in and of itself taught in Weiss et al. (Claims 21-24).

Claims 8 – 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al as applied to claim 1 above, and further in view of Geiser et al (US5797396). Whereas the former is silent as to Fourier analysis in their elliptical curvature and figure of merit determination, it would have been obvious in view of Geiser et al col. 22 lines 8 – 45 considered together with col. 30 lines 25-33 to use fast Fourier Transforms in border curvature analyses in order to efficiently compute curvatures. (claims 8, 9).

Claims 10, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al as applied to claim 1 above, and further in view of Abdelhak (US6939301) since whereas the former is silent as to trimester time frame for measurements, it would have been obvious in view of the latter col. 2 lines 57-63 to begin image-based monitoring for Down's Syndrome as called for in the former in the first trimester particularly since the parent(s) would wish to know to contemplate terminating the pregnancy. (claim 10).

Col. 3 lines 20-34 of Abdelhak suggests that other morphometric abnormalities may serve as markers for e.g. Downs or spina bifida. (claim 18).

Claims 18 – 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al as applied to claim 1 above, and further in view of Vintzileos et al (US5622176) insofar as whereas the former is silent as to biochemical/serum indicators, it would have been obvious in view of the latter, cols. 4 – 5 bridging, to use serum biochemical markers as well as nuchal swelling to confirm any anatomic biomarker(s)

prognosis in view of the enormous implications of this congenital diagnosis. (claims 18-20).

#### Response to Arguments

As noted above, the measured curvature values of the skull around the circumference serves as coefficients in the inverse determination which then serves to create the abnormality marker or risk index, and may properly be called a curvature coefficient at the given radial location about the fetal skull image for purposes of that function implementation since they are a numerical factor which multiplies the measured curvature radius at or near to the radial location to create the smooth inverse curve.

Wald (US6573103) is cited as of interest for its use of fetal nuchal translucency, crown rump length or biparietal diameter as ultrasound scan markers used in a MoM or multiples of median statistical risk calculation for Down's Syndrome presence.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.

FJJ:fjj

07032006



Francis J. Jaworski

Primary Examiner

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